REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

DISPOSITION OF CLAIMS

Claims 1-6, 8-44, and 61-63 are pending in this application. Claims 7 and 45-60 have been cancelled, and the limitation of cancelled claim 7 has been included in claim 1.

REJECTIONS UNDER 35 U.S.C. §112

Claims 43, 44, and 63 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Reconsideration of this rejection is respectfully requested.

With respect to claims 43 and 44, the Examiner asserts that the phrase "such as" renders the claims indefinite. Claims 43 and 44 have been amended to remove this phrase, as set forth above. Withdrawal of the indefiniteness rejection of claims 43 and 44 is respectfully requested.

With respect to claim 63, the Examiner asserts that it is not clear how claim 63 could require dry process conditions which are solvent-free when the method of claim 63 requires use of a suspension which has a solvent and is therefore wet.

The term "dry process conditions," as used in the instant application, implies degree of solvent concentration in the coating environment. A wet coating process has a relatively higher solvent concentration in the coating environment than a dry coating process. Both dry and wet coating processes start with coating suspensions including solvents. The dryness or wetness of a spray coating process can be accomplished by altering one or more of several parameters, such as inlet temperature, spray rate, agitation speed, air volume, exhaust pressure, and gun-bed distance. Thus, it is possible to run a wet or dry coating process starting with the same coating suspension, where the process parameters are then adjusted to achieve the desired process conditions. The process parameters necessary to achieve a wet or dry coating process typically change with the coating suspension formulation or the material being coated.

In paragraph [0009] of the specification as originally filed, dry processing condition is defined as one resulting in a coating efficiency of about 80% or less, and wet processing condition is defined as one resulting in a coating efficiency of about 85% or more. For clarity, claim 63 has been amended to recite, "wherein said coating of the intermediate dosage form is carried out under process conditions that result in a coating efficiency of about 80% or less." Withdrawal of the indefiniteness rejection of claim 63 is respectfully requested.

REJECTIONS UNDER 35 U.S.C. §102

I. Claims 1-6 and 12-16 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,419,952 (Wong et al.) Reconsideration of this rejection is respectfully requested.

Wong et al. do not disclose a coating suspension for an expandable osmotic layer of a dosage form satisfying all the limitations of claim 1. For example, Wong et al. do not disclose or teach a coating suspension having the properties "a film former, wherein the coating suspension includes from about 5 wt% to about 7 wt% of the film former" and "wherein the ratio of osmopolymer to osmotic agent included in the coating suspension is about 0.5:1 to about 0.7:1," as recited in amended claim 1.

In Example 1 of Wong et al., a coating solution formed as a suspension included methyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of approximately 8/25/1, where methyl cellulose is 0.4% of the coating suspension. In Example 4 of Wong et al., a coating solution formed as a suspension included hydroxyethyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of 3/2.9/9.1 (0.3/0.3/1). In Example 8 of Wong et al., a coating solution formed as a suspension included hydroxyethyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of 18.8/30.6/50.6 (0.4/0.6/1). In Examples 4 and 8, the amount of film former in the coating solution is not disclosed. None of these examples satisfy all the limitations of amended claim 1.

In view of the above, amended claim 1 is not anticipated by Wong et al. Claims 2-6 and 12-16, being dependent from claim 1, are likewise patentable in view of the foregoing

arguments. Withdrawal of the anticipation rejection of claims 1-6 and 12-16 in view of Wong et al. is respectfully requested.

II. Claims 45 and 58-60 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,800,422 (Dong et al.). These claims have been cancelled. Accordingly, the rejection of these claims is moot.

REJECTIONS UNDER 35 U.S.C. §103

Claims 1-62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wong et al. Claims 7 and 45-59 have been cancelled. Accordingly, the rejection of these claims is moot. Reconsideration of the rejection of claims 1-6, 8-44, 61, and 62 is respectfully requested.

In Example 1 of Wong et al., a coating solution formed as a suspension included methyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of approximately 8/25/1, where methyl cellulose is 0.4% of the coating suspension. In Example 4 of Wong et al., a coating solution formed as a suspension included hydroxyethyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of 3/2.9/9.1 (0.3/0.3/1). In Example 8 of Wong et al., a coating solution formed as a suspension included hydroxyethyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of 18.8/30.6/50.6 (0.4/0.6/1). In Examples 4 and 8, the amount of film former in the coating solution is not disclosed. Wong et al. do not disclose a coating suspension comprising a combination of an osmopolymer, an osmotic agent, and a film former, wherein the film former is about 5 wt% to about 7 wt% of the coating suspension and the ratio of osmopolymer to osmotic agent in the coating suspension is about 0.5:1 to about 0.7:1, as recited in claim 1.

The Examiner asserts that it would be prima facie obvious to a person of ordinary skill in the art at the time of the invention to vary the amounts of the materials in the coating solution of Wong et al. in order to optimize the expandable layer in order to alter the release profile of the dosage form.

The following is a factual showing of the existence of unexpected results in the combination of ranges recited in amended claim 1, which combination of ranges is not disclosed in Wong et al.

The applicant would like to draw the Examiner's attention to Examples 1 and 2 in the instant application. In these examples, capsules containing liquid active agent formulation were over-coated with eight coating suspensions under dry or wet process conditions to form intermediate dosage forms. The composition of the coating suspensions are detailed in Table 2 (FIG. 5) of the instant application. For convenience, the composition of the coating suspensions are reproduced in Table A below, along with the ratio of osmopolymer to osmotic agent and whether the coating suspension satisfies all the limitations of amended claim 1 or not. It should be noted that all the coating suspensions listed in Table A have osmopolymer to osmotic agent ratio within the range recited in claim 1 but not all the coating suspensions have film former amount within the range recited in claim 1.

Table A

Coating Suspension	NACMC (osmopolymer)	NATROSOL (film former)	NaCl (osmotic agent)	WATER	ETHANOL	NACMC:NACL	SATISFIES CLAIM 1
24_12	4.9	3	8.1	62.7	21.3	0.6:1	NO
24_13	4.9	3	8.1	62.7	21.3	0.6:1	NO
24_14	4.1	5	6.9	62.7	21.3	0.6:1	YES
24_15	4.1	5	6.9	62.7	21.3	0.6:1	YES
24_16	4.9	3	8.1	65.3	18.7	0.6:1	NO
24_17	4.9	3	8.1	65.3	18.7	0.6:1	NO
24_18	4.1	6	6.9	65.3	18.7	0.6:1	YES
24_19	4.1	5	8.9	65.3	18.7	0.5:1	YES

Table 2 (FIG. 5) of the instant application shows the percentage of cracked intermediate dosage forms resulting from each coating run using the coating suspensions above. None of the coating suspensions according to the claimed invention produced cracked intermediate dosage

forms under dry and wet process conditions. Coating suspensions 24_13 and 24_17 produced cracked intermediate dosage forms under wet process conditions but not under closely-monitored dry process conditions. The intermediate dosage forms were then over-coated with a semipermeable composition. The intermediate dosage forms coated with coating suspensions 24_13, 24_16, and 24_17 cracked when over-coated with semipermeable compositions under dry and wet process conditions. None of the intermediate dosage forms coated with coating suspensions according to the claimed invention cracked when over-coated with a semipermeable composition under dry and wet process conditions.

As shown factually above, the combination of claimed ranges recited in claim 1 exhibits unexpected results. The unexpected result is that the coating suspension according to the claimed invention produces intermediate dosage forms that are resistant to cracking under both dry and wet process conditions. The coating suspension according to the claimed invention thus facilitates commercial production of dosage forms incorporating a coated expandable osmotic layer. The result of the study described in the instant application shows that the claimed invention is more than a mere optimization.

According to the Examiner, "[t]he expected result would be for a suspension for coating a dosage form, the coating formed thereon, a dosage form comprising the coating, and a method of applying the coating wherein the composition of the suspension and the coating is optimized, according to Wong." According to the Examiner, "[t]he artisan would recognize that the controlled release profile will depend to a great exten[t] on the composition of the coating and would be motivated to optimize the composition of the coating in order to alter the release profile." It is noted herein that the dosage forms made from coating suspensions according to the claimed invention and the dosage forms made coating suspensions not according to the claimed invention produced comparable cumulative release profiles, as shown in FIG. 3 of the instant application. This does not support the argument that the controlled release profile depends to a great extent on the coating composition and an artisan wishing to alter the release profile would be motivated to optimize the coating composition.

From the foregoing, the criticality of the combination of claimed ranges recited in claim 1 has been demonstrated factually. This combination of claimed ranges is not disclosed by or obvious in view of Wong et al. Withdrawal of the obviousness rejection of claim 1 over Wong

et al. is respectfully requested. Claims 2-6 and 8-44, being dependent on claim 1, are likewise patentable in view of the foregoing arguments. Claims 61-62 recite a method of making a dosage form using the coating suspension recited in claim 1 and are patentable in view of the foregoing arguments. Withdrawal of the rejection of claims 2-6, 8-44, 61, and 62 is respectfully requested.

II. Claims 46-57 were rejected under 35 U.S.C. §103(a) as being obvious over Dong et al. These claims have been cancelled. Accordingly, the rejection of these claims is moot.

III. Claims 1-43 and 63 were rejected under 35 U.S.C. §103(a) as being obvious over Wong et al. in view of Dong et al. Claim 7 has been cancelled, but the limitation of cancelled claim 7 has been incorporated in claim 1. Reconsideration of the rejection of claims 1-6, 8-43, and 63 is respectfully requested.

As established above, claim 1 is not obvious over Wong et al. Claim 1 is also not obvious over Wong et al. in view of Dong et al. because that which is deficient in Wong et al. is not disclosed in Dong et al. In particular, the combination of these two references do not make obvious a coating suspension including a combination of "a film former, wherein the coating suspension includes from about 5 wt% to about 7 wt% of the film former" and "wherein the ratio of osmopolymer and osmotic agent included in the coating suspension is about 0.5:1 to about 0.7:1," as recited in claim 1 As demonstrated factually above, a coating suspension having film, osmopolymer, and osmotic agent in the range/ratio recited in claim 1 produces an unexpected result. Withdrawal of the rejection of claim 1 over Wong et al. in view of Dong et al. is respectfully requested. Claims 2-6 and 8-43, being dependent on claim 1, are likewise patentable in view of the foregoing arguments. Claim 63 recites a method of making a dosage form using the coating suspension of claim 1 and is patentable in view of the foregoing arguments. Withdrawal of the rejection of claims 2-6, 8-43, and 63 is respectfully requested.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated March 7, 2006, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC3162R1).

Respectfully submitted,

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